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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,854

12/18/2005

Vincent Ronfard

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1657

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,854	<b>Applicant(s)</b> RONFARD, VINCENT	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 21-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/01/08; 12/18/05</u> .                                       | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of group I, claims 1-20 in the reply filed on 12/12/2007 is acknowledged.

Claims 21-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 12/12/2007.

Claims 1-20 are under examination in the instant office action.

### ***Claim Rejections - 35 USC § 112***

Claims 1-20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 is indefinite because it is not particularly clear whether the claimed composition is dry or wet or solid or liquid. The claimed product is identified as a cell support and, thus, it appears to be solid. The claimed concentrations are presented in terms related to a liquid composition or to a kit for making cell support. Thus, concentrations as claimed have no meaning because final properties of the claimed product and/or final concentrations are uncertain as claimed.

Claim 3 is rendered indefinite by recitation of "Wm' ". In alternative, this is a spelling error.

Claim 9 recites the limitation "said protease inhibitor" in claim 1 but claim 1 does not recite any protease inhibitor. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,474,770 (Broly et al).

Claims are directed to a cell support for skin grafts comprising thrombin and fibrinogen wherein concentration of thrombin 0.5-2.5 U/ml. Some claims are further drawn to the use of thrombin at concentration 1-1.5 or 1.25 U/ml. Some claims are further drawn to the use of fibrinogen concentration 10-250 mg/ml. Some claims are further drawn to the use of thrombin at concentration 1.25 U/ml and to the use of fibrinogen concentration 75-150 mg/ml.

Some claims are further drawn to the use of protease inhibitor such as aprotinin at concentration 3,000 KIU/ml. Some claims are further drawn to incorporation of additional factor(s), cytokines, antibiotics, etc. in the cell support for skin grafts. Some claims are further drawn to incorporation of cell(s) such as keratinocytes in the cell support for skin grafts.

US 5,474,770 (Broly et al) discloses a biological cell support intended for skin grafts and comprising keratinocytes wherein thrombin, fibrinogen and aprotinin are used for making the cell support (whole patent including abstract and col. 4, lines 14-33). The cited patent discloses solutions with starting concentration(s) such as 10 IU/ml for calcic thrombin and 3000 KIU/ml for aprotinin. Although it is not particularly certain what is concentration of fibrinogen, the final composition has been demonstrated as suitable for supporting keratinocytes as intended for skin

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grafts and, thus, concentrations of each and all components are reasonably believed to be substantially the same as intended for the presently claimed cell support. Moreover, the cited patent teaches that concentration can be adjusted to obtain the desired consistency of the coagulated film (see abstract, for example). The cited patent also teaches incorporation of additional factor(s) for promoting cell multiplication such as EGF (col. 3, lines 10-11).

Thus, the cited US 5,474,770 is considered to anticipate the claimed invention because it teaches cell support composition made from the same components and intended for the same purpose as required for the presently claimed invention.

2. Claims 1-4, 12-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,989,215 (Delmotte et al).

Claims are directed to a cell support for skin grafts comprising thrombin and fibrinogen wherein concentration of thrombin 0.5-2.5 U/ml. Some claims are further drawn to the use of thrombin at concentration 1-1.5 or 1.25 U/ml. Some claims are further drawn to the use of fibrinogen concentration 10-250 mg/ml. Some claims are further drawn to the use of thrombin at concentration 1.25 U/ml and to the use of fibrinogen concentration 75-150 mg/ml. Some claims are further drawn to incorporation of additional factor(s), cytokines, antibiotics, etc. in the cell support for skin grafts. Some claims are further drawn to incorporation of cell(s).

US 5,989,215 (Delmotte et al) discloses a cell support or a bio-barrier composition as intended for tissue repairs including skin grafting procedures (col. 4, line 9). Thrombin and fibrinogen are used for making the composition at concentrations 1-300 IU/ml or 1-10 IU/ml for thrombin (col.14, lines 35-53) and 30-110 mg/ml for fibrinogen (col. 8, lines 5-7). Thus,

concentrations are within the presently claimed ranges. The cited patent also teaches incorporation of additional factor(s), cytokines, antibiotics, etc. in the composition (col.7, lines 8-25). The cited patent also teaches concentrations and conversion rates can be adjusted to modify pore size of in the resultant composition (col. 6, lines 41-60).

Thus, the cited US 5,989,215 (Delmotte et al) is considered to anticipate the claimed invention because it teaches cell support composition made from the same components and intended for the same purpose as required for the presently claimed invention.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,474,770 (Broly et al) and US 5,989,215 (Delmotte et al).

Both US 5,474,770 (Broly et al) and US 5,989,215 (Delmotte et al) disclose cell support compositions intended for tissue repairs including skin grafting procedures and concentrations of major components for making these compositions. Thrombin and fibrinogen concentrations disclosed by US'215 are clearly within the presently claimed ranges. Moreover, both cited patents teach and/or suggest that concentrations can be adjusted to obtain the desired consistency and/or pore size of coagulated film or of the final product.

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Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to adjust concentrations of thrombin and fibrinogen with a reasonable expectation of success in obtaining cell support of desired consistency as taught an/or suggested by the prior art. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

March 13, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/  
Primary Examiner, Art Unit 1657